

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of consultation based on PLISSIT model on Family Function and Sexual Quality of Life in patients with multiple sclerosis

Protocol summary

Study aim

Determining the effect of counseling based on PLISSIT model on family performance and sexual quality of life in patients with multiple sclerosis

Design

This study is a clinical trial with two groups (intervention and control), double blinded (the data analyst and participants) and randomized, with 30 patients in each group. In the intervention group, 4 counseling sessions Based on the PLISSIT model over 4 weeks And a 90-minute session per week is done individually; While control group patients will receive routine procedures. Family performance score and The Sexual Quality of Life score will be measured before and after the intervention.

Settings and conduct

This double blinded study (the data analyst and participants), will be done in the Kerman Medical Center of the Special Diseases.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women who complain of sexual dysfunction Ability to communicate in Persian language Diagnosis of Multiple Sclerosis according to neurologist confirmation Continuous attendance at counseling sessions Exit criteria: Failure to attend one of the meetings and the occurrence of a stressful incident Cases of recurrence of symptoms during the intervention so that it can be effective in our intervention Pregnancy, lactation or Pregnancy desire Suffering from other mental and physical illnesses Addiction to alcohol and drugs, according to the patient History of genital and breast surgery

Intervention groups

In the intervention group, 4 counseling sessions Based on the PLISSIT model over 4 weeks And a 90-minute session per week is done individually; While control group patients will receive routine procedures. Family performance score and The Sexual Quality of Life score will be measured before and after the intervention.

Main outcome variables

family performance and sexual quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151107024919N9**

Registration date: **2020-04-28, 1399/02/09**

Registration timing: **retrospective**

Last update: **2020-04-28, 1399/02/09**

Update count: **0**

Registration date

2020-04-28, 1399/02/09

Registrant information

Name

Batoul Tirgari

Name of organization / entity

Kerman Medical University of Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5207

Email address

b_tirgari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

2019-12-31, 1398/10/10

Actual recruitment end date

2020-03-08, 1398/12/18

Trial completion date

2020-04-08, 1399/01/20

Scientific title

The effectiveness of consultation based on PLISSIT model on Family Function and Sexual Quality of Life in patients with multiple sclerosis

Public title

The effectiveness of Sexual counseling on Family Function and Sexual Quality of Life in patients with MS

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women who complain of sexual dysfunction
Ability to communicate in Persian language
Diagnosis of Multiple Sclerosis according to neurologist confirmation
Continuous attendance at counseling sessions

Exclusion criteria:

Failure to attend one of the meetings and the occurrence of a stressful incident
Cases of recurrence of symptoms during the intervention so that it can be effective in our intervention
Pregnancy, lactation or Pregnancy desire
Suffering from other mental and physical illnesses
Addiction to alcohol and drugs, according to the patient
History of genital and breast surgery

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to allocate the subjects to the intervention and control groups, a randomized classification method is used, so that people in terms of Family performance score, Quality of sex life score, drug use by patients, type of disease, duration of illness, etc. are divided into groups. Subsequently, through the use of a simple method and using Excel software from each group, half of the subjects are placed in the intervention group and the other half are in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants and data analyst do not know which data is related to the intervention group and which data is related to the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

Street address

Medical Center of the Special Diseases, No. 78 Alley, Shahid Rajaei Street,

City

kerman

Province

Kerman

Postal code

7619875994

Approval date

2019-10-21, 1398/07/29

Ethics committee reference number

IR.KMU.REC.1398.303

Health conditions studied**1****Description of health condition studied**

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Family Function score

Timepoint

The Family Function score will be measured before and after the intervention at the end of the fourth week.

Method of measurement

Family functioning scale

2**Description**

Sexual Quality of Life score

Timepoint

Sexual Quality of Life score will be measured before and after the intervention at the end of the fourth week.

Method of measurement

Sexual Quality of Life-Female Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They receive 4 counseling sessions over 4 weeks, one 90-minute session per week, individually and face-to-face. The PLISSIT model will be used for consultation. The content of the counseling sessions includes the following: Session 1: Opportunity to Patient (P): At this stage, the therapist allows the patient to maintain the correct sexual traditions in order to remain sexually active, and at the same time encourages the patient to discuss the problems that it damages her sexual function. Session 2: Limited Information (LI): The patient is given information about the anatomical and physiological aspects of sexual function and information about MS and its side effects on sexual function. Session 3: Specific Suggestions (SS): At this stage, specific suggestions for the patient's specific concerns, counseling on the choice of alternative sex positions, and strategies to improve sexual satisfaction are provided. Session 4: Intensive Care (IT): In a few cases where people have underlying causes in their sexual problems that cannot be resolved in the first 3 steps, intensive treatment will be needed. By identifying these situations, the researcher will refer the patient to a specialist.

Category

Other

2

Description

Control group: Patients in the control group received routine methods such as exercise, relaxation techniques, etc.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical Center of the Special Diseases

Full name of responsible person

Batool Tirgari

Street address

Medical Center of the Special Diseases, No. 78 Alley, Shahid Rajaee Street,

City

Kerman

Province

Kerman

Postal code

7619875994

Phone

+98 34 3271 2001

Fax

+98 34 3271 2127

Email

b_tirgari@kmu.ac.ir

Web page address

<http://kmu.ac.ir/fa/snm>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

No 2, Research and Technology Dept., Ibsina Ave., Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3121 7213

Fax

Email

abpardakhti@kmu.ac.ir

Web page address

<http://kmu.ac.ir/fa/vcrt>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Batool Tirgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kerman University of Medical Sciences, Medical
University Campus, Haft- Bagh- Alavi Highway,
Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5207

Fax

+98 34 3132 5184

Email

b_tirgari@kmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Batool Tirgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kerman University of Medical Sciences, Medical
University Campus, Haft-Bagh-Alavi Highway, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5207

Fax

+98 34 3132 5184

Email

b_tirgari@kmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Batool Tirgari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Kerman University of Medical Sciences, Medical
University Campus, Haft-Bagh-Alavi Highway, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5207

Fax

+98 34 3132 5184

Email

b_tirgari@kmu.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Not applicable